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REMARKS/ARGUMENTS

Formal Matters

Claims 26-27, 29 and 31-37 are pending.

Claims 26-27, 29 and 31-37 were examined and rejected.

Claims 26 and 29 are amended for clarity. No new matter is added.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Oath/declaration

The Office asserts that the oath or declaration is defective because it was not executed in accordance with either 37 CFR § 1.66 or CFR § 1.68.

A declaration, attached hereto, was filed in this case on October 29, 2001, in response to the Notice to file Missing Parts. Since a declaration and not an oath was filed, 37 CFR § 1.66 is not relevant since 37 CFR § 1.66 relates to oaths only

With regard to CFR § 1.68¹, the Applicants respectfully that the declaration filed on October 29, 2001, meets the requirements of CFR § 1.68, and no new declaration needs to be filed.

If the Examiner maintains the assertion that the declaration filed on October 29, 2001, is defective, the Examiner is respectfully requested to specifically point out what aspects of the declaration renders it defective.

In the absence of a specific indication of the defect of the declaration, withdrawal of this objection is respectfully requested.

Rejection of claims under 35 U.S.C. § 112, first paragraph

Claims 26-27, 29 and 31-37 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which is not described in the specification in such a way as to enable one skilled in the art

¹ CFR § 1.68: "Declaration in lieu of oath. Any document to be filed in the Patent and Trademark Office and which is required by any law, rule, or other regulation to be under oath may be subscribed to by a written declaration. Such declaration may be used in lieu of the oath otherwise required, if, and only if, the declarant is on the same document, warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon. The declarant must set forth in the body of the declaration that all statements made of the declarant's own knowledge are true and that all statements made on information and belief are believed to be true. [49 FR 48416, Dec. 12, 1984, effective Feb. 11, 1985]"

to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Applicants respectfully traverse this rejection.

Specifically, the Office asserts that the specification fails to enable a method in which an intracellular target molecule may be identified in cells. The Office reasons that the specification provides only a general statement about how intracellular target molecules may be identified, and that such a method would contain numerous undefined and unpredictable steps.

With respect to the question of enablement, the MPEP is explicit: a patent specification need not teach, and preferably omits, what is well known in the art.² In other words, the MPEP explicitly discourages Applicants from describing in a patent specification that which was already known in the art.

The Applicants respectfully submit that once a bioactive peptide has been identified according to the screening step set forth in the claims, a wide variety of well known and routine biochemical and genetic methods would be available to one of skill in the art in order to identify the target for that bioactive peptide. For example, and as discussed on page 35 of the instant specification, such methods may employ biochemical means (e.g., immunoprecipitation or affinity columns) or genetic means (e.g., yeast/mammalian two-hybrid or three-hybrid systems). The Applicants respectfully submit that these methods were well known and routinely used prior to the instant priority date to identify binding partners for polypeptides of interest. In fact, two hybrid methods have been available since 1989 (Fields and Song *Nature* 1989 340:245-6; abstract submitted as Exhibit A) and were routinely used at the time of filing.

The methods to which the Office refers are therefore well known in the art. Pursuant to MPEP § 2173.04, the methods to which the Office refers need not be discussed in great detail by, and in fact are preferably omitted from, the instant patent application.

In view of the foregoing discussion, the Applicants respectfully submit that the instant specification enables a method in which an intracellular target molecule is identified because such methods are well known in the art.

The Applicants respectfully submit that this rejection has been fully addressed and may be withdrawn.

² MPEP at § 2164.01 "A patent need not teach, and preferably omits, what is well known in the art." citing *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Rejection of claims under 35 U.S.C. § 112, second paragraph

Claims 26-27, 29 and 31-37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

The Office asserts that claim 26 is unclear for omitting an essential step. Specifically, the Office asserts that claim 26 fails to recite a specific method by which target molecules may be identified. The Applicants respectfully traverse this rejection.

The Applicants respectfully submit that one of skill in the art would recognize what is meant by element c) of claim 26 (reciting “identifying an intracellular target molecule.....”) without reciting a specific method by which the target molecule is identified. This is all that is required to comply with 35 U.S.C. § 112, second paragraph, and, accordingly, this rejection may be withdrawn.

Further, the MPEP at § 2173.04³ very clearly states that breadth of a claim is not to be equated with indefiniteness.

The Applicants respectfully submit that element c) of claim 26 may be performed using any of a variety of biochemical or genetic identification methods that would be apparent to one of skill in the art. Element c) of claim 26 encompasses many methods and is not directed to any one identification method in particular. The Applicants respectfully submit that the question of whether a specific identification method should be recited in claim is a question of claim *breadth*, rather than indefiniteness. Pursuant to MPEP § 2173.04, the mere fact that more than one identifying method is encompassed by the term “identifying” in claim 26 does not necessarily render the claim indefinite.

In other words, the Applicants respectfully submit that the Office is equating *breadth* of claim 26 (i.e., whether or not the claim is directed to a variety of identification methods or any one identification method in particular) with *indefiniteness* of claim 26. Since MPEP § 2173.04 states that claim breadth is not to be equated with claim indefiniteness, this rejection may be withdrawn.

The Applicants respectfully submit that this rejection has been adequately addressed and may be withdrawn.

³ MPEP § 2173.04: “Breadth Is Not Indefiniteness. Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.”

The Office asserts that the use of terminologies such as “intracellular bioactive peptide”, “randomized peptide”, “a peptide” and “transdominant bioactive peptide” provide for confusion and ambiguity. The Applicants respectfully traverse this rejection.

Without wishing to acquiesce to the correctness of this rejection and solely to expedite prosecution, the term “a peptide” has been amended to recite a “randomized peptide”.

The Applicants respectfully submit that this rejection has been adequately addressed and may be withdrawn.

The Office asserts that the screening step b) of claims 19 and 26 (the “screening” step) is not positively recited. The Applicants respectfully traverse this rejection.

Without wishing to acquiesce to the correctness of this rejection and solely to expedite prosecution, the screening steps of claims 19 and 26 have been amended to recite “screening said plurality of cells *to identify a cell that has an altered phenotype*”.

The Applicants respectfully submit that this rejection has been adequately addressed and may be withdrawn.

The Office asserts that claim 29 is indefinite for reciting the terms “first portion” and “second portion” without giving structure for those portions. The Applicants respectfully traverse this rejection.

The Applicants respectfully submit that the use of such terms as “first” and “second” is standard in the construction of patent claims.

To evidence this fact, the Applicants searched for patents that issued in 2002 with claims having the words “first” and “second” using the search string *((ACLM/first AND ACLM/second) AND ISD/20020101->20021231)*. The Applicants identified **83425** issued patents that contain these terms. Since only **184530** patents issued in 2002, the terms “first” and “second” are used in almost half of the patents that issued that year.

The Office appears to argue that the terms do not provide any structural characteristic to the objects to which they refer (i.e., two portions of a presentation structure). However, this is not so: the claims require that the first portion is bound to the N-terminus of a candidate peptide and the second portion if bound to the C-terminus of the candidate peptide. As such, the terms do provide a structural characteristic of the object to which what the terms “first portion” and “second portion” refer: they are bound to the different ends of a candidate peptide.

The Applicants respectfully submit that this rejection has been adequately addressed and may be withdrawn.

The Office asserts that claim 27 is confusing because elements (e) and (f) appear to have been reversed. The Applicants respectfully traverse this rejection.

The Applicants respectfully submit that where a claim does not expressly state or necessarily imply the sequence of all or some steps, that claim would cover the steps performed in any order or simultaneously. Accordingly, elements (e) and (f) may be performed in any logical order. Practiced in their current order, elements (e) and (f) would encompass, for example, biochemical assays that involve isolating the bioactive agent and then binding the target of the peptide to the peptide. In reverse, the bioactive peptide may be first bound to its target, and then peptide isolated. Both methods may be used to identify a target for the peptide and both methods are encompassed by the claim.

In view of the foregoing, the Applicants respectfully submit that claim 27 is not indefinite. Even if the claim is interpreted to require that the steps (e) and (f) are performed in the order set forth (i.e., (e) before (f)), the claim encompasses many standard biochemical methods.

The Applicants respectfully submit that this rejection has been adequately addressed and may be withdrawn.

The Office asserts that “It is not clear how the candidate nucleic acids is linked to a nucleic acid encoding at least one fusion partner, in the absence of said manipulative, positive step in the base claim.”

The Applicants respectfully request clarification of this rejection. In particular, the Applicants request clarification of what the Office means by the phrase “said manipulative, positive step” since the meaning of that phrase is not clear, especially considering that the word “said” implies that a “manipulative, positive step” is discussed somewhere else in the Office Action or is specifically recited in the claims. The phrase “manipulative, positive step” is found nowhere else in the Office Action nor is this precise language used in the claims. As such, the Applicants respectfully submit that the rejection is not clear.

Further, the Applicants respectfully submit that there is no basis, either in the MPEP or current caselaw, to require a step of making a composition, if that composition is to be used in a method claim.

The Applicants respectfully submit that this rejection should be withdrawn, or explained more clearly in the next Office Action.

If this rejection is to be maintained in the next Office Action, the Applicants respectfully request that the next Office Action be non-final Office Action.

Rejection of claims under 35 U.S.C. § 102

Claims 26-27, 29 and 31-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Jensen (U.S. published application 20010053523).

The Applicants respectfully submit that Jensen cannot be cited under 35 U.S.C. 102(e), and, accordingly, this rejection may be withdrawn.

MPEP § 2136.03 discusses the effective date of a publication under 35 U.S.C. § 102 in great detail. According to MPEP § 2136.03⁴, the effective date of a publication resulting from an international application depends on whether the international application was filed prior to, or on or after, November 29, 2000. If a publication results from an international application filed prior to November 29, 2000, the effective date of that publication under §102(e) is the actual filing date of the later-filed U.S. application that claimed the benefit of the international application.

May 31, 1996 (the filing date of Jensen's international application) is prior to November 29, 2000. Accordingly Jensen is a U.S. application publication of a patent application that claims benefit of an international application filed in the PCT prior to November 29, 2000 as set out in MPEP § 2136.03(C)(3)..

Since MPEP § 2136.03 explicitly states that a US application publication that claims the benefit of an international application that was filed prior to November 29, 2000, is to be applied as a reference under §102(e) as of the actual filing date of the later-filed U.S. application that claimed the benefit of the

⁴ 2136.03: Critical Reference Date:

(C) If the international application has an international filing date prior to November 29, 2000, apply the reference under the provisions of 35 U.S.C. 102 and 374, prior to the AIPA amendments:

(1) For U.S. patents, apply the reference under 35 U.S.C. 102(e) as of the earlier of the date of completion of the requirements of 35 U.S.C. 371(c)(1), (2) and (4) or the filing date of the later-filed U.S. application that claimed the benefit of the international application;

(2) For U.S. application publications and WIPO publications directly resulting from international applications under PCT Article 21(2), never apply these references under 35 U.S.C. 102(e). These references may be applied as of their publication dates under 35 U.S.C. 102(a) or (b);

(3) For U.S. application publications of applications that claim the benefit under 35 U.S.C. 120 or 365(c) of an international application filed prior to November 29, 2000, **apply the reference under 35 U.S.C. 102(e)**

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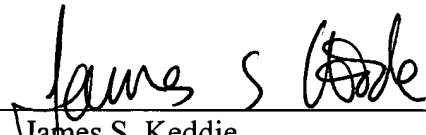
international application, the earliest §102(e) date for Jensen is May 15, 2001, which is **after** the priority date of the instant application. Furthermore, the publication date of Jensen of December 20, 2001 is also after the priority date of the instant application. Therefore, Jensen is not available as prior art against the present claims under any subsection of §102.

The Applicants respectfully submit that this rejection has been adequately addressed, and may be withdrawn.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number RIGL-004CON4.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 06-07-04

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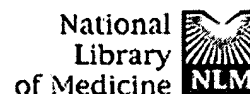
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Enclosures: Declaration filed October 29, 2001
Exhibit A: abstract of Fields and Song Nature 1989 340:245-6

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as of the actual filing date of the later-filed U.S. application that claimed the benefit of the international application. (emphasis added)

09/919,635 - Exhibit A



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1: Nature. 1989 Jul 20;340(6230):245-6.

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A novel genetic system to detect protein-protein interactions.**Fields S, Song O.**

Department of Microbiology, State University of New York at Stony Brook, Stony Brook 11794.

Protein-protein interactions between two proteins have generally been studied using biochemical techniques such as crosslinking, co-immunoprecipitation and co-fractionation by chromatography. We have generated a novel genetic system to study these interactions by taking advantage of the properties of the GAL4 protein of the yeast *Saccharomyces cerevisiae*. This protein is a transcriptional activator required for the expression of genes encoding enzymes of galactose utilization. It consists of two separable and functionally essential domains: an N-terminal domain which binds to specific DNA sequences (UASG); and a C-terminal domain containing acidic regions, which is necessary to activate transcription. We have generated a system of two hybrid proteins containing parts of GAL4: the GAL4 DNA-binding domain fused to a protein 'X' and a GAL4 activating region fused to a protein 'Y'. If X and Y can form a protein-protein complex and reconstitute proximity of the GAL4 domains, transcription of a gene regulated by UASG occurs. We have tested this system using two yeast proteins that are known to interact--SNF1 and SNF4. High transcriptional activity is obtained only when both hybrids are present in a cell. This system may be applicable as a general method to identify proteins that interact with a known protein by the use of a simple galactose selection.

PMID: 2547163 [PubMed - indexed for MEDLINE]

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